

Original Article

***Application of Consent to Perform Medical Actions (Informed Consent) Doctors in Medical Services at Hospitals in Palu City***

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**ABSTRACT**

*This research aims to know how about the implementation Informed Consent is executed on medical services in the hospitals in the city of Palu appropriated to rule of Minister of Health Number 290/MENKES/PER/III/2008, and to know the barriers which are faced in the implementation Informed Consent on medical services in the hospitals in the city of Palu. This research is an empirical legal research or non doctrinal research. The techniques of collection of legal materials is done through observations, interviews, and distributing questionnaires to the respondents by purposive sampling method. All data collected were described and analyzed descriptively, by looking the data percentage collected, and showed in the form of frequency distribution table, and then classified the muchly percentage from each respondents, ethical feasibility from the Research Ethics Commission of the Poltekkes of the Ministry of Health Palu Number 005.1/KEPK-KPK/1/2023. The result showed that the implementation of Informed Consent on medical services in the hospitals in the city of Palu is appropriated to the Rule of minister of health Number 290/MENKES/PER/III/2008 about the lacks of its implementation, that come from medical nurses as well as from patients. Suggestion that given is to make team for applying informed consent in the hospital that consist of specialis surgery, specialis anaesthesia, psykology, and a standart operational.*

**Keywords:** *Informed Consent, Medical Services.*

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**INTRODUCTION**

Development in the health sector encourages a socially and economically productive life. The definition of health is an action or a series of actions taken by the government and/or community to maintain and improve the level of public health through the prevention of disease, promotion of health, treatment of disease, and restoration of health. Law Number 36 of 2009 Concerning Health regulates this<sup>1</sup>.

One of the actions in the health sector is medical action, where this action is usually carried out by a person who works as a doctor. When a doctor performs an action on a patient, it is not uncommon to take an action which is called a "medical error", although this term

cannot be put directly into a legal context, such as an error, because it can be interpreted as (legal) negligence. Meanwhile, according to J. Guwandi, "medical error" is not always associated with sanctions, medical error can be forgiven, even though according to legal standards it is considered severe<sup>2,3</sup>.

Medical law recognizes and uses the term "malpractice/medical negligence"; but this is not the same as the term medical error, because one of the benchmarks is the result that arises from the actions of a person. In the medical field, it was previously believed that the consequences of medical action could be separated from the doctor-patient relationship; it's just that now that understanding has been abandoned. Nowadays, there is an understanding that there is a connection with the

way in which health services are provided and the medical treatment is given because it will affect the acceptance or consequences that arise<sup>4,5</sup>.

Recent publications related to informed consent in health services show increasing concern about the importance of informed consent<sup>6-9</sup>. Informed consent has been the subject of several analyses from the perspectives of health services, disease states, and the medical community<sup>10-15</sup>. Informed consent is a part that every doctor must carry out correctly, clearly and precisely, because this is a legal protection tool for both doctors and patients, so that if unwanted things happen during the procedure at least the patient has received an explanation correctly and properly and he agreed by signing the informed consent<sup>16</sup>.

In the Indonesian Medical Council Regulations concerning guidelines for upholding the discipline of the medical profession in 2011 it is stated that every doctor in carrying out medical actions must obtain approval from the patient or next of kin or guardian or guardian. Philosophical foundation. Informed consent is required because: (1) Demands from patient's autonomy; (2) Protecting the patient's status as a human being; (3) Prevent coercion and deception; (4) Encourage self-criticism of doctors; (5) Assisting rational processes in making decisions (process rational decision-making); (6) Educating the community<sup>5,17,18</sup>.

In connection with the implementation of informed consent, it should also be noted that there are 21 expert doctors at Anutapura General Hospital with an average number of operations per month in 2013 of 157 patients; and expert doctors at Undata Hospital totaling 33 people with an average number of operations per month in 2013 of 251 patients.

Based on the description above, the problems to be discussed in this study are as follows: (1) How is the application of informed consent in hospital health services in the city of Palu according to Permenkes 290/MENKES/PER/III/2008. (2) What are the obstacles encountered in applying informed consent to hospital services in Palu City.

## METHOD

Finding hypotheses regarding the incidence and operation of law in society is the

goal of this research, which takes the form of empirical studies. This research was carried out at Anutapura General Hospital and Undata Hospital which had applied informed consent in Palu City. The implementation of research i was for 6 months, namely January - July 2014. The population in this study all characteristics related to research variables, while the population unit was specialist doctors at the Undata Regional General Hospital Palu and Anutapura General Hospital Palu, totaling 54 people (21 specialist doctors from Anutapura General Hospital and 33 specialist doctors from Undata Hospital), nurses accompanying 20 specialist doctors and 24 patients. The sample in this study were 20 specialist doctors who performed surgery and 20 assistant nurses, as well as 24 patients at Undata General Hospital Palu and Anutapura General Hospital Palu. The number of this sample already represents the number of specialist doctors in the two hospitals. The sampling technique is purposive sampling. Data types and sources. The interview method used in this study was a structured interview where the researcher prepared questions and asked the respondents. In this study, the authors conducted direct interviews with doctors, patients and nurses. The results that have been obtained are collected, analyzed. ethical feasibility from the Research Ethics Commission of the Poltekkes of the Ministry of Health Palu Number 005.1/KEPK-KPK/1/2023.

## RESULTS

Based on interviews with informants, there are certain limitations related to the capacity of the patient and/or patient's family who are eligible to receive and give consent to medical action. Not all patients may give statements, either agree or disagree. The conditions for a patient who may give a statement are:

1. The patient is an adult: here there are still differences of opinion about the age limit for adulthood, but in general a limit of 21 years can be used. Patients who are under this age limit but are married include the criteria for adult patients.
2. The patient is conscious: This implies that the patient is not unconscious, in a coma, or has his consciousness disturbed due to the influence of drugs, psychological pressure,

or other things. Means, patients must be able to communicate naturally and smoothly.

3. The patient is in good sense: So the person most entitled to determine and give a statement of consent to a medical action plan is the patient himself, if he meets the 3 criteria above, not his parents, children, husband/wife, or anyone else. However, if the patient does not meet the 3 criteria mentioned above, he is not entitled to determine and express his approval of the medical action plan that will be carried out on him. In cases like this, the patient's rights will be represented by the family guardian or legal guardian. For example, if the patient is still a child, then those who have the right to give consent are their parents, or their uncle/aunt, or other legal guardian order. If the patient is married, but in a state of unconsciousness or loss of common sense, then the husband/wife is the most entitled to express consent if he/she agrees.
4. Rights of the patient's husband/wife: For several types of medical actions related to couple life as husband and wife, the statement of consent to the medical action plan must involve the consent of the patient's husband/wife if the husband/wife is available or can be contacted for this purpose. In this case, of course the husband/wife must also meet the criteria of "conscious and sane". Several types of medical action, for example actions on the reproductive organs, family planning, and medical actions that can affect the sexual or reproductive abilities of these patients.
5. In an emergency: The process of providing information and requesting approval for a medical action plan may not be carried out by a doctor if the patient's situation is in an emergency. In this condition, the doctor will prioritize actions to save the patient's life. This life-saving procedure must still be carried out in accordance with applicable standards of medical services/procedures accompanied by upholding professionalism. After the critical period has passed and the patient is able to communicate, the patient has the right to receive complete information about the medical action he has experienced.
6. Does not imply impunity: The implementation of this informed consent simply states that the patient (and/or their legal guardian) has agreed to a plan of medical action to be carried out. The

implementation of the medical procedure itself still has to comply with medical professional standards. Any negligence, accident, or other form of error that arises in carrying out the medical action can still cause the patient to feel dissatisfied and has the potential to file a lawsuit. Informed consent does state that the patient already understands and is ready to accept the risks in accordance with what has been previously informed. However, this does not mean that the patient is willing to accept any risks and losses that will arise, let alone state that the patient will not claim any losses that may arise. Informed consent does not make a doctor immune to the law for events caused by negligence in carrying out medical procedures.

7. Related to invasive actions: a guardian is needed (a person who according to law replaces another person who is not yet an adult to represent in carrying out legal actions, or a person who according to law replaces the position of a parent); landlady (a person who is obliged to supervise and take responsibility for the personal life of other people, for example the leader of a hostel from a child of nomads, the head of an RT from an immature RT helper).

Based on interviews with patients and doctors it can be concluded that informed consent has several purposes, namely:

1. Protect users of medical services (patients) by law from all medical actions that are carried out without their knowledge, as well as arbitrary actions of medical service providers, malpractice actions that are contrary to patient rights and medical professional standards, as well as misuse of sophisticated equipment that requires a fee tall;
2. Providing legal protection for medical practitioners from unreasonable patient demands, as well as the consequences of unexpected medical procedures, for example against risks of treatment that are unavoidable even though doctors have acted in accordance with medical professional standards.

## DISCUSSION

Juridically, Article 1 number 7 Permenkes Number 290 of 2008 confirms that

a competent patient is an adult patient or not a child according to laws and regulations or has/had been married, is not disturbed by physical awareness, is able to communicate normally, does not experience developmental delays (retarded) mentally and do not experience mental illness so that they are able to make decisions freely. Furthermore, Article 7 paragraph (2) of the Minister of Health Regulation Number 290 of 2008 provides other limitations as follows: in the case of a patient who is a child or an unconscious person, an explanation is given to his family or the person accompanying him<sup>19</sup>.

*“It is a delicate matter to decide whether a patient has more than the minimum acceptable level of understanding, in order to claim that informed consent has been obtained. In my opinion, the threshold is that individuals should feel they are able to make a free decision about study participation. For patients to make choices that are as autonomous as possible, given the circumstances, in an emergency such as acute myocardial infarction, they should be given information that focuses on a few essential aspects of the study, including their right to decline participation. When patients have more severe symptoms, the following choices are faced: either no research is conducted on these kinds of patients; only a low level of understanding is considered sufficient for moral or legal consent in this situation; or patients are included in research without their immediate consent”*<sup>20</sup>.

The opinions above indicate how complicated it is to decide whether a patient has more than the minimum acceptable level of understanding, to claim that informed consent has been understood. There must be certain standards to determine the level of patient understanding. For patients to make the best possible autonomous choices, it is necessary to know their own situation, for example in an emergency such as acute myocardial infarction, they must be provided with information that focuses on the important aspects of it, including their right to refuse medical action. When patients have more severe symptoms, the choice of medical action needs to be based on the type of patient; understanding at a low level is generally considered sufficient for a moral or legal agreement in such situations<sup>21</sup>.

The researcher is of the view that the alternative options proposed by law without including imperative clauses have caused the

application of informed consent to be adjusted based on the patient's condition and the doctor's assessment. This will potentially lead to medical disputes in the future if the results obtained in the treatment are not as expected. In other words, there needs to be normative firmness that provides limitations on the act of informed consent<sup>22</sup>.

*Can: Any person who is capable of giving consent or, in the event that the person is not capable of giving consent, by his or her legal representative, must freely decide to participate in a clinical trial. If the person concerned is unable to write, oral consent in the presence of at least one witness may be given in lieu of written consent*<sup>23</sup>.

If examined, the conditions put forward by the Minister of Health above regarding the form of informed consent are very restrictive and limitative with the main aim of saving the patient's life. Researchers are of the view that although the form of informed consent is given an alternative according to the patient's condition, it is necessary to emphasize the written character of the informed consent so that it has the strength of evidence that binds doctors and patients.

Researchers also contend that even an oral agreement is acceptable because informed consent is essentially a process of communication between doctors and patients regarding an agreement on a medical action that the doctor will conduct for the patient (there is a full explanation by the doctor). The written informed consent form must be signed in order to reaffirm the previous understanding. A thorough explanation serves to empower the patient to make an informed decision based on his own preferences. As a result, the patient also has the option of declining the suggested medical treatment. Additionally, patients have the right to get a second opinion from the medical professional who is treating them.

Although in its implementation informed consent has received written legitimacy, such agreement cannot be used as an excuse to justify deviant medical treatment. Consent (informed consent) of the patient or his family does not waive legal risks for the emergence of unwanted consequences in terms of medical treatment that is correct and not deviant.

Even though there is such an agreement that if medical treatment is carried out incorrectly to the point of causing unwanted

consequences, the doctor is also still burdened with responsibility for the consequences. Informed consent actually has a dual function. For doctors, informed consent can create a sense of security in carrying out medical actions on patients, as well as being used as self-defense against all possible claims or lawsuits from patients or their families against the risks posed. Whereas for patients, informed consent is a form of respect for their rights by doctors and can be used as a justification for suing or suing doctors as a result of deviations from the doctor's practice from the intention of giving a health service approval letter <sup>22</sup>.

It should be noted that the discussion regarding the form of informed consent is closely related to the agreement created between the doctor and the patient. As previously known, in the context of an effort to recover, patients will visit both private doctors and hospitals. In this case, it can be distinguished between patients who have actually entered into an agreement, and patients who have not entered into an agreement. This distinction is made clear in distinguishing from the existence of the agreement, which imposes rights and obligations on the parties entering into an agreement <sup>24</sup>.

Based on the results of the study it was known that as many as 3 patients (12.5%) had refused because the information about the medical procedure given was not understood. Meanwhile, from the doctor's point of view, as many as 2 doctors (7.69%) had experienced refusal to take medical action. The researcher is of the opinion that the consent to medical action is strongly supported by the completeness of detailed information regarding all the prerequisites in Article 8 of the Minister of Health Regulation Number 290 of 2008 <sup>19</sup>.

Related to this, as many as 19 patients (79.1%) stated that the information obtained was poorly understood because many used medical languages that was foreign to the patient or patient's family; while 100% of doctors stated that the information provided was completely clear. This indicates that it is necessary to establish a standardization of information delivery that can be fully understood by patients. *It is presumed that the person signing the consent form has read and fully understands what it contains. Since there is no recognized way to gauge how much a person understands the provided information, it is very difficult to determine whether this is*

*actually the case. As a result, it is reasonable to suppose that certain misunderstandings do arise (USM Website). Many people sign the consent form without fully understanding what they are doing*<sup>23</sup>.

It is assumed that the individual who signs the consent form does so with full understanding of what the consent form says. However, it is very difficult to evaluate because no method has been devised to measure the level of understanding that patients have little knowledge of the information provided. Thus, it can be assumed that there is a degree of misunderstanding that occurs. Many people sign consent forms without being fully aware of what they are signing. Researchers argue that explanations are given in language and words that can be understood by patients according to their level of education and 'maturity', as well as their emotional situation. The doctor must try to check whether his explanation is understood and accepted by the patient. If not, the doctor must repeat the description again until the patient understands correctly. Doctors should not try to influence or direct patients to accept and agree to medical treatment that doctors actually want <sup>25</sup>.

Judging from the theory of legal protection, the government has actually attempted to provide protection for legal subjects in the form of legal instruments, both preventive and repressive in nature, especially regarding the implementation of informed consent. In other words, the government applies the function of law, namely the concept in which law can provide justice, order, certainty, benefit and peace.

However, when viewed from the theory of the legal system, there are still many fundamental weaknesses related to the implementation of informed consent, which include weaknesses in terms of legal structure (quality of medical services), legal substance (not yet strictly regulated), and legal culture (level of public awareness and knowledge less about informed consent).

## CONCLUSION

Based on the results of the research and discussion, several conclusions were obtained. The application of informed consent in health services in Palu City Hospitals is in accordance with the Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning.

Approval for Medical Practice, but there are still certain deficiencies in its application, both from health workers as well as from patients. The obstacles encountered in the application of informed consent to hospital services in Palu City consist of the competency aspect of health services where there are still nurses who help to provide information regarding medical actions to be carried out by doctors and the inability of patients or their families to understand the medical information provided. given, also the unit has not been formed and which consists of a special team for the implementation of informed consent

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#### CONFLICTS OF INTEREST:

We certify that there are no conflicts of interest in the conduct of the study, the creation of the articles, or the analysis of the study's findings.

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